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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/624,885 | 07/24/2000 | Albert Edge | DNI-029 | 6245 |

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[REDACTED] EXAMINER

DECLOUX, AMY M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1644 | |

DATE MAILED: 03/25/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|-----------------------------|----------------------------|------------------|
| Offic Action Summary | Application N . | Applicant(s) |
| | 09/624,885 | EDGE, ALBERT |
| | Examin r Amy M. DeCloux | Art Unit 1644 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 16 January 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 43-49 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 43-49 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Applicant's amendment filed 1-16-03 (Paper No. 18) is acknowledged and has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

MAINTAINED Claims 43-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Allen et al. (1991) (J. Cell Physiology 149:525-535).

Allen et al teach a composition of skeletal muscle satellite cells which, when cultured in media with serum for 1 day contained at least 5% fibroblasts, and up to 15 % fibroblasts in cultures that were cultured from 10-20 days, said time frames of 1 day and 7-14 days encompassing 5-10 doublings (see entire article, including the Abstract and page 526). Additionally, the satellite cell "clones" are taught by Allen to be low density compositions of satellite cells, and that said compositions appear to be essentially free of myotubes until day 10 of culture, (see entire article including column 2 of page 526). Allen et al teach also that said compositions which contained BrdU contained no fusion, and thus would be free of myotubes.

Therefore, the referenced article anticipates the claimed invention. It is noted that the specification discloses that "skeletal myoblasts" includes satellite cells, see page 5, lines 20-22 of the instant specification.

Response to Arguments

Claims 43-48 replace now cancelled claims 6-15 and 18. Applicant traverses the rejection on the grounds that Allen does not teach or suggest compositions that are substantially free of myotubes, and refers to page 528 of the article by Allen et al which Applicant states that their standard four day cultures as containing many myotubes. However, the Examiner notes that said compositions that additionally comprised BrdU contained no fusion, and thus would be free of myotubes.

Applicant further contends that Allen et al does not teach or suggest a composition that contains at least 5% fibroblasts. However the examiner notes that Allen teaches that said composition contains fibroblasts that ranged in percentage from approximately 5% in 24 hour cultures to 15% in mature cultures (see entire article, including lines 26-29 of the Abstract).

Regarding dependent claims that specify that the recited compositions are grown in vitro for at least 7 days, Applicant contends that the 21 day growth period mentioned in Allen was for colonies, not for collections of cells including satellite cells and fibroblasts. However, the examiner notes that said "clones" are taught by Allen to be low density compositions of satellite

Art Unit: 1644

cells which absent evidence to the contrary contain fibroblast cells, as evidenced by the presence of fibroblast cells in the starting culture. Allen further teaches that these compositions were cultured for up to 20 days, until myotubes were visible.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 43-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 43-49 are drawn to a composition comprising isolated skeletal myoblasts and isolated fibroblast cells, the composition being substantially free of myotubes, and claims 44-49 recite the further limitation that said composition comprises at least 5% fibroblasts. Applicant's disclosure of a composition of cells isolated from skeletal muscles and grown on laminin with EGF for three days, and a composition of cells isolated from skeletal muscles and grown on collagen with FGF for three days, does not provide sufficient support for the recited composition wherein said composition being substantially free of myotubes. The proscription against the introduction of new matter in a patent application (35 U.S.C.132 and 251) serves to prevent an applicant from adding information that goes beyond the subject matter originally filed. Specifically, Applicant has carved out a subgenus of a composition comprising isolated skeletal myoblasts and isolated fibroblast cells, the composition being substantially free of myotubes, as recited in claims 43-49, and wherein said composition comprises at least 5% fibroblasts as recited in claims 44-49. By carving out said subgenus, Applicant is introducing elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. See, e.g., In re Lukach, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); In re Smith, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads) (see MPEP 21.63). There is no written description of the claimed invention in the specification or claims as originally filed. Thus the claimed invention constitutes new matter.

Claim 49 which is drawn to a composition comprising human cells, is included in this rejection because there is not a single exemplification of said composition. Applicant states in the Remarks Section of the Amendment filed 1-16-03, that the procedure described by Allen et al for preparing compositions clearly gives different results (ie different percentages of satellite cells, fibroblasts, myotubes etc) for cells of different origins ie rat vs bovine. Therefore, the

Art Unit: 1644

instant disclosure of a method for making the recited compositions comprising cells derived from non-human species does not provide adequate written description for the recited composition comprised of cells derived from the human species.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 872-9306 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.
Patent Examiner,
March 18, 2003

Pat J. Nolan
Patrick J. Nolan, Ph.D.
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